DEC 122008

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

JAMES N. HATTEN, Clerk By: Vicenta Clerk

STIEFEL LABORATORIES, INC.,

Civil Action No.

08-nv-37**73**

Plaintiff,

JURY DEMANDED

v.

BROOKSTONE PHARMACEUTICALS, L.L.C.

Defendant.

CAP

ORIGINAL COMPLAINT

Plaintiff Stiefel Laboratories, Inc. ("Stiefel") files this Original Complaint against Defendant Brookstone Pharmaceuticals, L.L.C. ("Brookstone" or "Defendant") for false advertising and unfair competition under Section 43(a) of the Lanham Act, and common law unfair competition.

PARTIES

1. Plaintiff Stiefel is a corporation organized under the laws of Delaware. Stiefel is headquartered in Coral Gables, Florida. Stiefel markets BREVOXYL®-4 Gel (4% Benzoyl Peroxide, NDC No. 00145-2374) and BREVOXYL®-8 Gel (8% Benzoyl Peroxide, NDC No. 00145-2384) (collectively "BREVOXYL Gel") to doctors throughout the United States.

2. Upon information and belief, Defendant Brookstone is a limited liability company organized under the laws of Georgia and having its principal place of business at 9005 Westside Parkway, Fulton County, Alpharetta, Georgia 30004. Brookstone markets, promotes, advertises, offers for sale, sells, and distributes products known as "BPO 4% Gel" and "BPO 8% Gel" (collectively "BPO Gel") to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in the Northern District of Georgia. Brookstone may be served with process by serving a copy of the Complaint on its registered agent for service of process: Kevin J. Loechl, 1150 Monarch Plaza, 3414 Peachtree Rd. NE, Atlanta, Georgia 30326.

JURISDICTION AND VENUE

- 3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, 1338, and 1367, and 15 U.S.C. §§ 1116 and 1121, as this case arises under the Lanham Act. Additionally, the amount in controversy exceeds \$75,000 and involves citizens of different states.
- 4. The exercise of personal jurisdiction in Georgia is proper because Brookstone is a Georgia limited liability company, and regularly transacts business in the State of Georgia. Moreover, acts giving rise to Plaintiff's causes of action

have occurred in the State of Georgia and, more particularly, within the Northern District of Georgia. Specifically, Brookstone markets, promotes, advertises, offers for sale, sells, and/or distributes BPO Gel to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in the Northern District of Georgia Brookstone has purposefully and voluntarily placed BPO Gel into the stream of commerce with the expectation that it will be purchased by consumers in the Northern District of Georgia. Consumers have purchased and continue to purchase BPO Gel in the Northern District of Georgia. Furthermore, Brookstone falsely promotes BPO Gel as generic substitutes for BREVOXYL to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in the Northern District of Georgia.

5. Venue is proper in the Northern District of Georgia under 28 U.S.C. § 1391.

BACKGROUND

Stiefel Develops BREVOXYL to Help Millions of Americans Suffering from Acne Vulgaris

6. Acne vulgaris is the most common of all skin diseases, affecting approximately seventeen million Americans. It is especially prevalent among

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adolescents; approximately 80% to 95% of adolescents develop acne of some degree. Acne lesions form when hair follicles become plugged with dead skin cells and oil produced by the sebaceous glands. Bacteria trapped in the blocked pores causes inflammation, visible on the skin surface as reddened pimples, pustules and cysts. Acne most commonly appears on the face, back, upper chest, and shoulders. It is a significant source of misery and disfigurement, and can be difficult to treat even when the patient is under the care of trained dermatologist.

- 7. Founded in 1847, Stiefel is the world's largest independent pharmaceutical company specializing in dermatology. Stiefel develops, manufactures and markets innovative prescription and non-prescription dermatological products for the treatment of a wide range of dermatologic conditions and diseases including acne vulgaris, rosacea and seborrheic dermatitis. Among Stiefel's products is BREVOXYL Gel, a prescription drug containing 4% or 8% benzoyl peroxide as an active ingredient in a patented formulation. BREVOXYL Gel is indicated for the treatment of mild to moderate acne vulgaris.
- 8. Benzoyl peroxide is an antibacterial agent that has been used for nearly five decades in the treatment of acne vulgaris. Applied as a topical preparation, benzoyl peroxide is absorbed through the skin into the hair follicles where it kills acne-causing bacteria, reduces inflammation, and promotes peeling

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of the outer layers of the skin. Most topical benzoyl peroxide preparations contain suspended crystalline particles of benzoyl peroxide that are water insoluble. When applied, water and other volatile solvents evaporate, leaving a residue of benzoyl peroxide particles on the skin. These formulations are more stable than products containing benzoyl peroxide in its dissolved form; however, for some patients the benzoyl peroxide crystals can cause local irritation and sensitization at the point of contact with the skin.

9. BREVOXYL Gel is a topical preparation consisting of 4% or 8% benzoyl peroxide in a aqueous gel vehicle. It is marketed as a prescription product in compliance with a tentative final FDA monograph for topically-applied, overthe-counter (OTC) acne products containing benzoyl peroxide. BREVOXYL Gel's base contains dimethyl isosorbide, an organic solvent that is water soluble, but less volatile than water. The dimethyl isosorbide dissolves benzoyl peroxide crystals on the skin, reducing the potential for contact irritation and increasing the

¹See Topical Drug Products Containing Benzoyl Peroxide; Required Labeling, 60 Fed. Reg. 9554 (Feb. 17, 1995). Prior to 1991, benzoyl peroxide was a proposed Category I product (generally recognized as safe and effective). In 1991, the FDA reclassified benzoyl peroxide as a Category III product (more data needed) because of concerns that benzoyl peroxide and sunlight might promote cancer. The FDA requested, and an industry task force conducted additional safety studies. In the meantime, the FDA adopted its expert committee's unanimous recommendation that acne products containing benzoyl peroxide remain available. See Id.

bioavailability of the benzoyl peroxide. In tests, BREVOXYL Gel has demonstrated significant efficacy in the treatment of acne, with lower irritancy than other topical benzoyl peroxide products.

and building brand awareness. Among other things, Stiefel tested BREVOXYL Gel to ensure that it would be safe and effective treatments for their labeled indications. Additionally, Stiefel's representatives meet with doctors and other prescribers to provide information on the use and benefits of BREVOXYL Gel. Stiefel has provided many samples of BREVOXYL Gel to doctors across the country. As a result of Stiefel's efforts, BREVOXYL Gel has become a leading prescription product with annual combined sales of approximately \$2 million.

Brookstone Develops and Markets Its Knock-Off Product to Exploit BREVOXYL Gel's Success

- 11. Defendant Brookstone is an Georgia-based pharmaceutical company that develops, manufactures, markets, sells and distributes what it calls "niche and overlooked generic" versions of popular brand name prescription drugs.
- 12. Upon information and belief, sometime in 2008, Brookstone saw an opportunity to exploit the reputation and success of BREVOXYL Gel by creating a knock-off version that it calls BPO Gel.

- 13. Upon information and belief, Brookstone began marketing its knock-off products in 2008. Upon information and belief, BPO Gel is not manufactured using BREVOXYL's patented formula. BPO Gel does not contain dimethyl isosorbide. Upon information and belief, prior to launching BPO Gel, Defendant did not perform any tests to determine if these products were bioequivalent or therapeutically equivalent to BREVOXYL Gel, nor did Defendant spend the time and resources necessary to ensure that BPO Gel would be as effective as BREVOXYL Gel.
- 14. Despite the absence of clinical equivalency testing, Brookstone nevertheless markets BPO Gel to drug wholesalers, distributors, pharmacies, pharmacists and others as a generic equivalent to and substitute for BREVOXYL Gel. Brookstone has had BPO Gel linked to BREVOXYL Gel in drug dispensing databases and price systems that represent a major drug marketing communications channel to pharmacists and chain store buyers, and are used by pharmacists to decide which drug product to dispense when filling a prescription.
- 15. In its advertising and promotion to drug databases and pricing systems, wholesalers, distributors, retailers and pharmacists, Brookstone has made no effort to differentiate BPO Gel from BREVOXYL Gel other than on the basis of price. Specifically, in commercial advertising and promotion, Brookstone

describes itself as a company developing and selling "affordable, high-quality, specialty generic" prescription drug products. Upon information and belief, in commercial advertising and promotion, Brookstone states and implies that BPO Gel is a generic version of BREVOXYL Gel and labels BPO Gel as a generic equivalent to BREVOXYL Gel. For example, in its September 2, 2008 press release to the pharmaceutical trade, Brookstone claimed described its BPO gel as the "First-to-Market Generic" for BREVOXYL Gel. Upon information and belief, in its commercial advertising and promotion, Brookstone does not inform drug databases and pricing systems, wholesalers, distributors, pharmacies or pharmacists that there are no comparative studies showing that its products are therapeutically equivalent or bioequivalent to BREVOXYL Gel.²

16. Upon information and belief, Brookstone seeks to capture market share from BREVOXYL Gel by encouraging generic substitution of BPO Gel for BREVOXYL Gel.

² Much of the marketing of a generic drug occurs "under the radar" in targeted communications with drug wholesalers, retailers and others, who are encouraged to "link" the generic product to the branded drug in their databases. Like the rest of the consuming public, plaintiffs are not privy to those communications; however, as is typical of most marketing campaigns, for every publicly available statement or piece of information there are many unseen and unheard sales pitches and additional pieces of evidence that will only come to light through discovery.

Defendant's efforts have had their intended effect; based upon Defendant's commercial advertising and promotion, drug databases and pricing systems as well as wholesalers, distributors, formularies and retail pharmacy chains have "linked" BPO Gel as a generic equivalent to BREVOXYL. As a result of Defendant's commercial advertising and promotion, BPO Gel is now substituted as a generic for BREVOXYL in pharmacies in the Northern District of Georgia and across the country. This could not occur unless Defendant had successfully created the false impression among drug databases and pricing systems, wholesalers, distributors, formularies, retail pharmacy chains and pharmacists that BPO Gel is genuinely generic to and substitutable for BREVOXYL Gel.

BPO Gel is not a Generic Equivalent to or Substitute for BREVOXYL Gel

- 18. A pharmacist presented with a doctor's prescription for a brand-name drug may fill that prescription by dispensing the drug prescribed or an identical, "generic" version of the drug. This process is known as generic drug substitution.
- 19. Generic drugs are therapeutically equivalent to their branded rivals.

 To be therapeutically equivalent, the products must be pharmaceutically equivalent

 e.g. have the same active ingredients, strength, and dosage form and they must
 be bioequivalent deliver the active ingredients to the body at the same rate and in
 the same amount.

- 20. For pharmacists and other medical professionals, these two requirements pharmaceutical equivalence and bioequivalence ensure that a generic drug substituted for the prescribed brand-name drug is truly interchangeable and will provide the patient with the treatment the doctor ordered. This is critical because the doctor, not the wholesaler, distributor or pharmacist, is responsible for making the appropriate treatment decisions and tracking the patient's progress.
- 21. State law governs pharmacy practice, including generic drug substitution.³ Most state laws explicitly require that a substitute drug be both pharmaceutically equivalent and bioequivalent to the drug prescribed.
- 22. Notwithstanding Brookstone's marketing efforts, BPO Gel is not a generic equivalent to or substitute for BREVOXYL Gel. BREVOXYL Gel and BPO Gel are manufactured by different companies using different formulations, and have different physical properties. Moreover, upon information and belief,

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³ The U.S. Food and Drug Administration (FDA) does not regulate generic drug substitution. However, to assist pharmacists and others in making drug product selection decisions, the FDA regularly publishes a list of interchangeable prescription drugs in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The Orange Book lists thousands of brand name drugs along with the generic drugs that the FDA has concluded are therapeutically equivalent. However, the Orange Book does not list every brand name or generic drug. For example, it does not include BREVOXYL Gel and thus cannot list BPO Gel as a therapeutic equivalent to BREVOXYL Gel.

Brookstone has not performed or commissioned any studies comparing the effectiveness of BPO Gel to BREVOXYL Gel and has no clinical evidence that BPO Gel is bioequivalent or therapeutically equivalent to BREVOXYL Gel. This is especially significant given that BPO Gel does not use BREVOXYL Gel's patented formulation or contain dimethyl isosorbide. Topical products that are formulated differently, such as these, are subject to differences in bioavailability and cannot be presumed bioequivalent to one another. BPO Gel is not bioequivalent to or therapeutically equivalent to BREVOXYL Gel.

- 23. Stiefel have been and will be harmed by Defendant's literally and impliedly false and misleading advertising and unfair competition. Brookstone's marketing efforts have misled consumers into believing that BPO Gel is a generic equivalent to and substitute for BREVOXYL Gel. As a result, substitutions of BPO Gel for BREVOXYL Gel have eroded and will continue to erode BREVOXYL Gel's sales and goodwill as well as Plaintiff's revenues.
- 24. Stiefel does not and cannot control the safety, effectiveness or quality of Defendant's inferior products. Thus, doctors and patients who suffer bad experiences with BPO Gel that is substituted for prescriptions of BREVOXYL Gel are likely to think less of both Plaintiff and its products.

COUNT 1: <u>VIOLATION OF LANHAM ACT SECTION 43(A)</u> (FALSE ADVERTISING)

- 25. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-24, above.
- 26. Defendant Brookstone markets BPO Gel to drug databases and pricing systems, wholesalers, distributors, drug store chains, pharmacies, and others in interstate commerce as a generic substitute for BREVOXYL Gel. Brookstone intends for potential customers to believe that its inferior products are equivalent to and substitutable for BREVOXYL Gel.
- are literally and/or impliedly false and misleading. BPO Gel is not generic to or substitutable for BREVOXYL Gel. Brookstone's promotional claims violate Section 43(a) of the Lanham Act, which provides in relevant part that "any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act."

- 28. Additionally, Brookstone is liable for false advertising under the Lanham Act because it knows or has reason to know that drug databases and pricing systems, wholesalers, distributors, drug store chains, and others falsely describe BPO Gel as generic equivalents to and substitutes for BREVOXYL Gel to pharmacists, but continues to supply BPO Gel to those entities.
- 29. By reason of Defendant's conduct, Stiefel has suffered and will continue to suffer, damage to its business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Stiefel is entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of BPO Gel, and recovery of Stiefel's costs and reasonable attorneys' fees incurred in this action.
- 30. Defendant's acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Stiefel to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.
- 31. Unless enjoined by this Court, Defendant's acts will irreparably injure Stiefel's goodwill and erode their market share. Pursuant to 15 U.S.C. § 1116, Stiefel is entitled to preliminary and permanent injunctive relief to prevent Defendant's continuing acts.

COUNT 2: <u>VIOLATION OF LANHAM ACT SECTION 43(A)</u> (UNFAIR COMPETITION)

- 32. Plaintiff refers to and incorporate herein the allegations of Paragraphs 1-31, above.
- 33. Stiefel has become uniquely associated with BREVOXYL Gel, and the public identifies Stiefel as the source for BREVOXYL Gel.
- 34. Brookstone has marketed and continues to market its inferior knock-off products as generic equivalents to and substitutes for BREVOXYL Gel, and in doing so, has deceived, misled, and confused consumers. This has enabled Brookstone to trade off of Stiefel's reputation and good will.
- 35. Brookstone's acts constitute unfair competition in violation of Section 43(a) of the Lanham Act.
- 36. Additionally, Brookstone is liable for unfair competition under the Lanham Act because it intentionally induced and/or knew or had reason to know that drug databases, wholesalers, distributors, drug store chains, and others falsely describe BPO Gel as a generic to and substitute for BREVOXYL Gel to pharmacists but continued to sell BPO Gel to those entities.
- 37. By reason of Defendant's conduct, Stiefel has suffered and will continue to suffer damage to its business, reputations, and goodwill. Pursuant to

- 15 U.S.C. § 1117, Stiefel is entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of BPO Gel, and recovery of Stiefel's costs for this action.
- 38. Defendant's acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Stiefel to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.
- 39. Unless enjoined by this Court, Defendant's acts will continue to cause immediate and irreparable harm to Stiefel for which there is no adequate remedy at law. Pursuant to 15 U.S.C. § 1116, Stiefel is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

COUNT 3: <u>VIOLATION OF THE GEORGIA UNIFORM DECEPTIVE PRACTICES</u> <u>ACT</u>

- 40. Stiefel refers to and incorporates herein the allegations of Paragraphs 1-39.
 - 41. O.C.G.A. § 10-1-372 provides that:
 - (a) a) A person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he:
 - (1) passes off goods or services as those of another;

- (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;

. . .

(5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;

. . .

(7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

. . .

- (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.
- 42. O.C.G.A. § 10-1-373 provides a private right of action to enforce the provisions of O.C.G.A. § 10-1-372.
- 43. In the course of their business, Defendants, by and through their false and misleading representations of fact and conduct concerning BPO Gel, respectively, have engaged in and continue to engage in deceptive trade practices in violation of O.C.G.A. § 10-1-372.

- 44. Defendants have willfully engaged in their actions regarding BPO Gel, respectively, knowing them to be deceptive.
- 45. By reason of Defendants' conduct, Stiefel has suffered and will continue to suffer damage to its business, reputation and goodwill.
- 46. Pursuant to O.C.G.A. § 10-1-373, Stiefel is entitled to enjoin Defendants' unlawful conduct as well as recover reasonable attorneys' fees.

COUNT 4: COMMON LAW UNFAIR COMPETITION

- 47. Plaintiff refers to and incorporate herein the allegations of Paragraphs 1-46, above.
- 48. With full knowledge of Stiefel's BREVOXYL Gel, Brookstone has made false and misleading explicit and implicit representations to wholesalers, pharmacists, and others, that its products are generic to BREVOXYL Gel, and that they can be substituted for prescriptions for BREVOXYL Gel.
- 49. Brookstone's selective and misleading comparisons of BPO Gel with BREVOXYL Gel, and omission of relevant facts, are likely to cause confusion, mistake, or deception about the nature, characteristics, and qualities of their knock-off products in comparison, connection, or association with BREVOXYL Gel.
- 50. Brookstone knows, or in the exercise of reasonable discretion should know, that its marketing program encourages the sale and substitution of its knock-

off products for prescriptions of BREVOXYL Gel and is likely to result in the improper substitution of BPO Gel for BREVOXYL Gel, and the deception of doctors, pharmacists, patients, and others, about the nature, characteristics, and qualities of BPO Gel in comparison, connection, or association with BREVOXYL Gel.

- 51. Brookstone's actions are willful and have been undertaken with the purpose of deceiving consumers.
- 52. As a result of such conduct, Defendant has caused, and unless enjoined by this Court, will continue to cause consumer confusion as to the equivalence and interchangeability of its knock-off products with BREVOXYL Gel.
- 53. Stiefel is entitled to damages for Defendant's unfair competition, an accounting of profits made on sales of BPO Gel, and recovery of Stiefel's costs of this action.
- 54. As a result of Defendant's conduct, Stiefel has suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer damage to its business, reputation, and goodwill for which it is entitled to relief.

PRAYER FOR RELIEF

Plaintiff prays for the following relief:

- A. A judgment and order that Defendant, its agents, servants, employees, attorneys, successors, and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from directly or indirectly falsely advertising or promoting BPO Gel, or inducing others to substitute BPO Gel for prescriptions of BREVOXYL Gel;
- B. A judgment and order that Defendant, its agents, servants, employees, attorneys, successors, and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation, or distribution of BPO Gel in such fashion as to suggest that these products are therapeutically equivalent, pharmaceutically equivalent, or bioequivalent to BREVOXYL Gel, or can be freely interchanged with or substituted for prescriptions of BREVOXYL Gel;
- C. A judgment and order that Defendant, its agents, servants, employees, attorneys, successors, and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from placing, and are

ordered to remove, information linking BPO Gel to BREVOXYL Gel in any drug dispensing databases and/or pricing systems in the United States;

- D. A judgment and order that Defendant must include in any advertisement or promotion comparing BPO Gel with BREVOXYL Gel, whether oral or written, a notice in location and typeface as prominent as the comparison itself, that BPO Gel "is not therapeutically equivalent, pharmaceutically equivalent, or bioequivalent to BREVOXYL Gel. Therefore, the substitution of this product for BREVOXYL Gel may violate state law";
- E. A judgment and order that Defendant must take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of BPO Gel or BREVOXYL Gel including without limitation the placement of corrective advertising to prevent the inducement of others from substituting BPO Gel for prescriptions of BREVOXYL Gel;
- F. A judgment and order granting Plaintiff such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics, or qualities of BPO Gel or from inducing others to substitute BPO Gel for prescriptions of BREVOXYL Gel;
- G. A judgment and order requiring Defendant to pay Plaintiff damages under 15 U.S.C. § 1117(a) in the amount of Plaintiff's actual and consequential

damages and any profits of Defendant resulting from its advertisements and marketing of BPO Gel and BP10-1;

- H. A judgment and order requiring Defendant to pay the costs of this action under 15 U.S.C. § 1117(a);
- I. A judgment and order finding that this is an exceptional case and requiring Defendant to pay Plaintiff additional damages equal to three times the actual damages awarded Plaintiff pursuant to 15 U.S.C. § 1117(a), as well as all of Plaintiff's reasonable attorneys' fees under 15 U.S.C. § 1117(a), O.C.G.A. § 10-1-373 and any other applicable law;
- J. The Court enter an order finding that Defendant's actions or omissions demonstrate malice, or aggravated or egregious fraud, requiring Defendant to pay Plaintiff punitive damages pursuant to the common law of the State of Georgia;
- K. A judgment and order requiring Defendant to pay Plaintiff's prejudgment and post-judgment interest on the damages awarded; and
 - L. Such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands that all issues be determined by jury.

Dated: December 22, 2008

Respectfully submitted,

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